

### **REMARKS/ARGUMENTS**

Claims 19-27 remain pending in the application. No amendments to the claims are proposed at this time.

The issues raised in the current Official Action relate to evidence provided in a declaration filed October 27, 2009, alleged lack of written description for terminology used in the claims, asserted to be "new matter" as well as a single prior art-based rejection based upon newly cited documents. Appropriately, the rejection has not been made final.

On page 2, the Examiner states that the Declaration by the joint inventor Thomas Landh is not persuasive because it does not mention that the instant invention is a reversed phase microemulsion. The Examiner also states that the prior art teaches an emulsion having a polar phase mixed with non-polar lipids and surfactants which would lead to a reversed phase emulsion. The Examiner objects that the declaration from Inventor Landh does not recite the components, amounts or conditions used, so that he cannot tell whether the compositions of the prior art are the same as the current invention.

With regard to the first point, the Examiner's attention is directed to paragraph 12 of inventor Landh's declaration which refers to the "reversed phase microemulsions of the type recited in the claims" of the current application. This is clearly a statement that the instant inventions are reversed phase microemulsions.

Moreover, this point is explicitly covered in the declaration by inventor Wollmer, dated 18 August 2008. Paragraph 3 therein states that "the microemulsions of the present invention are "reversed phase" as opposed to "normal" type". The second sentence of paragraph 8 therein states that "All examples are necessarily reversed-phase water-in-oil type microemulsions as is evident to one skilled in the art.". It is clear, therefore, that the declarations of both inventors do, in fact, state that the instant invention is a reversed phase microemulsion. It is difficult to see how much clearer the inventors could be on this point.

This point is also highly relevant to the Examiner's maintained objection that the phrase "reversed phase" has no basis in the application as filed and therefore constitutes addition of matter. As explained in applicants' previous responses and in declarations by two of the joint inventors, the compositions of the invention are inherently reversed-phase and this is implicitly and **inherently** disclosed throughout the application as filed. The reversed-phase nature of the

microemulsions of the current invention is an intrinsic property, which would be clear to the skilled worker in the field, and the stipulation of this property in the claims therefore has basis throughout the application as filed. It is no extension of the scope of the application as originally filed to specify that the microemulsions of the current invention are reversed-phase, because they could not be anything other than reversed phase, and this fact would be immediately and abundantly clear to the skilled worker. It is noted that the Examiner has not commented on the supporting publication by Leser *et al.* in this regard.

With regard to the second of the Examiner's points relating to the declaration, it is noted that the Examiner still appears to be using the terms "emulsion" and "microemulsion" interchangeably. As explained in applicants' previous response, although these terms appear linguistically similar they are technically quite different. Both terms relate to mixtures of immiscible liquids, but emulsions and microemulsions are structurally and functionally quite different. This is discussed at some length in the declaration by inventor Landh. It is essential to appreciate that the present claims relate to *reversed phase microemulsions* and not to either *emulsions* or anything of *normal phase* (oil-in-water). The differences between emulsions and microemulsions are also explained in the cited prior art by Linn *et al.* (column 1, lines 10-35). The Examiner does not dispute these technical differences but also has taken no account of them in the current Office Action.

Turning to the substantive rejections, applicants are pleased to note that the Examiner's previous rejections on the basis of the combination of Baker *et al.* and Wright *et al.* have been withdrawn.

The Examiner has raised newly cited prior art, US 4797273 (Linn *et al.*), US 5897876 (Rudnic *et al.*) and US 5665700 (Rudnic *et al.*) which are combined by the Examiner to argue that the claims are obvious. The Applicant respectfully disagrees for the reasons already submitted in the form of argument and inventor declarations. These are reiterated below as they apply to this new prior art.

The present invention relates to the inventors' work with certain (reversed phase) microemulsions in entrapping airborne particles. In particular, the inventors have surprisingly established that the claimed compositions form "non-breaking" layers at a body surface that

serve to entrap airborne particles and thus prevent conditions, such as allergies, which may be caused by these.

Linn *et al.* relates to skin moisturizing microemulsions. These are water-in-oil microemulsions comprising 1-8 wt.% sunscreen, 15-79 wt.% of microemulsion-forming surfactant, 15-79 wt.% polysiloxane and 5-50 wt.% skin humectant (column 2, lines 14-20) and are designed for complete absorption into the skin.

Several specific microemulsions are disclosed in columns 3-4, one of which comprises 3-35 wt.% vegetable oil, 20-80 wt.% microemulsion-forming surfactant, 10-70 wt.% polysiloxane and 5-50 wt.% skin humectant.

In contrast, the reversed phase microemulsion of the current invention requires:

- 5-35 wt.% of a non-polar animal or vegetable oil;
- 10-55 wt.% of a polar solvent selected from water, buffer, alcohol or mixtures thereof;
- at least one surfactant from polysorbate, poloxamer or fatty acid polyoxyethylene;
- and 20-50 wt.% monoacyl glycerol.

There is no suggestion in Linn that the microemulsions could be formed without the major polysiloxane or skin humectants components, and in particular nothing to suggest a monoacylglycerol, a non-polar vegetable oil and a surfactant could be used in combination without the other key components. This is emphasized by the fact that monoacylglycerols and poloxamers must be selected from very long lists and non-polar vegetable oils are not disclosed.

Linn *et al.* discloses various vegetable oils (column 5, lines 46-50) but does not teach that these must be non-polar.

A very long list of surfactants is disclosed for use by Linn *et al.* (column 6, lines 14-34), including sorbitols and poloxamers. However, there is no teaching that these are particularly advantageous or any incentive for their selection from the list.

In addition, there is no disclosure of the incorporation of a monoacyl glycerol into the microemulsions of Linn *et al.* This is the component of the present claims having the largest minimum level.

Linn *et al.* teaches compositions which "leave little residue on the surface of the skin" and are not irritants when the correct balance of surfactants is used (column 7, lines 51-56). Linn *et al.* teaches that their compositions are particularly important because of their ability to increase the rate of penetration of the moisturizing agents incorporated to the areas of skin in need of moisturization, i.e the dermis and epidermis (column 8, lines 20-31), their ability to increase epidermal thickening (column 8, lines 31-35), and their ability to increase the penetration of a macroemulsion moisturizer subsequently applied (column 8, lines 36-52).

Rudnic *et al.* teaches a water-in-oil microemulsion made up of an oily phase, an aqueous phase and a surfactant. The oily phase is disclosed as made up of long chain fatty acids or esters/alcohols thereof. An extremely large number of possible compounds are listed in column 3, line 55 to column 4, line 59. Many suitable surfactants are listed in column 5, lines 10-44. The aqueous phase is simply disclosed as being "mainly" water (column 3, lines 51-52).

Rudnic does not disclose the necessary components of the current invention, or their relative proportions. In particular, the incorporation of 20-50 wt.% monoacyl glycerol is not disclosed or taught therein.

The pharmaceutical formulations of Rudnic *et al.* are for oral delivery (see abstract). In contrast, Linn *et al.* relates to a topical product for sub-dermal effect. There is thus no reason for the skilled worker to combine these documents. There is no incentive provided by Rudnic *et al.* for the skilled man to modify the teachings of Linn *et al.* and, crucially, the necessary teaching required to reach the current microemulsions from the microemulsions of Linn *et al.* is not supplied by Rudnic *et al.* A skilled worker would not look to Rudnic if making dermal compositions, nor to Linn if making oral compositions. Even if both were consulted however, there is no suggestion that reversed phase microemulsions are formable from the very specific components and proportions recited in the present claims. To reach this combination, the skilled worker must try thousands of combinations from two unrelated documents and then optimize each for a function not proposed in either document. This is simply not a viable task.

Similar reasoning applies to Cho *et al.* This document also relates to oral administration of pharmaceutical compositions, and fails to disclose or teach the necessary modifications to the microemulsions of Linn *et al.*

The microemulsions of Linn *et al.* are ultimately effective at the sub-dermal level, rather than on the surface of the skin. In fact they are not intended to leave a residue on the surface and it is taught that the lack of surface residue is an advantage of these compositions.

In contrast, the microemulsions of the current invention are intended to coat the surface of a mucosal membrane, in order to substantially enclose and "trap" airborne particles (see paragraphs [0026-30] of the current application). The problem to be solved here may be defined as the prevention of airway diseases and/or inflammation of mucosal membranes. The solution to this problem is the microemulsion of the current invention.

When seeking to solve the problem of the prevention of airway diseases, the skilled worker would not consider documents regarding oral administration of pharmaceuticals, such as Rudnic *et al.* and Cho *et al.*. Neither would he consult teachings regarding the application of cosmetics such as moisturizer or sun-screen at a sub-dermal level, as in Linn *et al.* There is absolutely no reason why the skilled worker would even consult, let alone combine these documents.

For the reasons given above, the applicant believes that the current claims are inventive over the prior art, both alone and in combination.

Should the examiner require further information, please contact the undersigned.

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 14-1140.

Respectfully submitted,

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